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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/792,307

03/03/2004

Andrew J. Griffith

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06/06/2006

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EXAMINER

WAX, ROBERT A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/792,307	Applicant(s) GRIFFITH ET AL.	
	Examiner Robert A. Wax	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-12,20-23 and 32-45 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,20-23 and 34-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-8, 11, 12, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-8, 11 and 12 and the species of SEQ ID Nos.: 3 and 4 in the reply filed on March 30, 2006 is acknowledged. The traversal is on the ground(s) that there is no undue burden involved in examining all groups together, particularly with respect to the elected DNA and the pharmaceutical composition comprising the DNA. This is not found persuasive because there is, in fact, a large extra examination burden that would be required to examine the claims to a pharmaceutical composition comprising DNA. The utility of a pharmaceutical composition containing DNA is obviously gene therapy. Claims to gene therapy often lack enablement since the technique is unpredictable and requires undue experimentation to practice while no such rejection is needed with the instant claims. With respect to the other groups, each of them requires a search totally different from that required for the elected group, which is why there would be an undue burden to examine those inventions along with the elected one.

The requirement is still deemed proper and is therefore made FINAL.

Examiner appreciates the reminder of rejoinder practice and assures applicants that those procedures will be followed upon the determination that the elected invention is patentable.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 3, 5 and 6 are again rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kurima et al. (Reference AK on the PTO-1449 filed March 3, 2004).

This rejection was explained in the previous Office action. The BLAST search done by applicants retrieved the entry for gi 20304092, which corresponds to GenBank Accession number NM_080751. When Examiner searched for that gi number the website gave a page with the message, "The record has been replaced by NM_080751.2." Clicking on that link showed, of course, NM_080751.2, which shows the same sequence as the original sequence search results, accession number AF417580, which shows all 3169 nucleotides. The sequences of NM_080751.2 and AF417580 are the same. Therefore, Kurima et al. do in fact teach a sequence that is 100% identical to SEQ ID No.: 3. The alignment from the previously performed sequence search and the relevant pages from the NCBI website are included as an appendix to this Office action so that applicants may review them.

Claim Rejections - 35 USC § 103

4. Claims 7, 8, 11, 12, 32 and 33 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Kurima et al.

This rejection was explained in the previous Office action.

Double Patenting

5. Claims 1,3, 5-8, 11, 12, 31 and 32 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 7-9, 11, 12, 15, 16, 23 and 24 of copending Application No. 10/487,887. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicant argues that this rejection is moot and should be withdrawn because claims 7-9, 11, 12, 15, 16, 23 and 24 of copending Application No. 10/487,887 are nonelected and withdrawn. Examiner disagrees that the rejection should be withdrawn since the claims are not yet canceled from the copending application. This rejection will be withdrawn either when the instant application is allowable but for the remaining double patenting rejection or the claims are canceled from the copending application.

Response to Arguments

6. Applicant's arguments filed March 30, 2006 have been fully considered but they are not persuasive. Examiner believes that all arguments have been addressed above.

Conclusion

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Robert A. Wax', with a stylized, cursive script.

Robert A. Wax
Primary Examiner
Art Unit 1653

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